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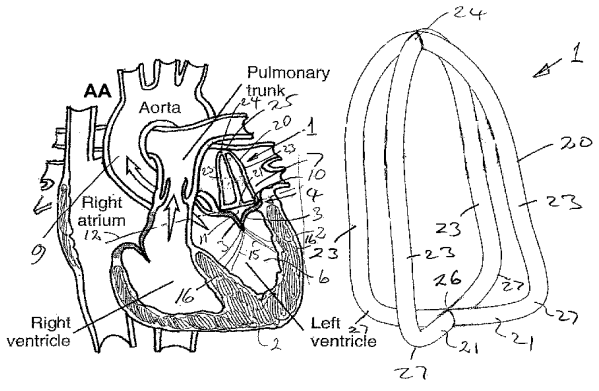
(54) Title: A DEVICE FOR CORRECTING INVERSION OF THE LEAFLETS OF A LEAFLET VALVE IN THE HEART



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(57) Abstract: A device for correcting mitral valve regurgitation comprises a cage structure formed of super-elastic wire for locating in the left atrium (7) of a heart (2) of a subject for preventing inversion of valve leaflets (3) of the mitral valve (4). The device (1) comprises a pair of abutment members (21) for engaging an annulus (10) of the mitral valve (4) and for extending diametrically across a valve opening (11) of the annulus (10) for preventing the valve leaflets (3) extending through a valve plane (12) defined by the mitral valve (4) into the left atrium (7). Four retaining members (23) extend from the abutment members (21) to an engagement portion (24) which engages a portion (25) of the heart wall (16) for retaining the abutment members (21) in engagement with the mitral valve (4). The device (1) is suitable for catheter placement in the left atrium (7), and is resiliently erectable from a collapsed state to an erect state when discharged from a catheter into the left atrium (7).

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"A device for correcting inversion of the leaflets of a leaflet valve in the heart"

The present invention relates to a device for correcting inversion of the leaflets of a leaflet valve in the heart of a subject, and in particular, though not limited to a device for correcting mitral valve regurgitation in the heart of a subject. The invention also relates to use of the device for correcting inversion of the leaflets of a leaflet valve in the heart, and also to the use of the device for correcting mitral valve regurgitation.

Mitral valve regurgitation in the heart of a subject results from the failure of the mitral valve to prevent backflow of blood from the left ventricle to the left atrium of the heart when the mitral valve is in a closed state. The mitral valve, which is located between the left ventricle and the left atrium comprises a valve annulus which defines a mitral valve opening through which the left ventricle and the left atrium communicate. A pair of valve leaflets, namely, an anterior valve leaflet and a posterior valve leaflet extend from the valve annulus into the left ventricle and are moveable between an open state for facilitating blood flow through the valve opening from the left atrium to the left ventricle, and a closed state for isolating the left ventricle from the left atrium. The valve leaflets are passive valving members, in that they open and close in response to pressure to which they are subjected by blood flow resulting from the pumping action of the heart. Free ends of the valve leaflets in the left ventricle are connected to the muscular wall of the heart by fine but strong fibrous cords, which limit movement of the valve leaflets, and in particular, constrain the leaflets to move together from the open state into the closed state. Additionally, the fibrous cords act on the valve leaflets for preventing the valve leaflets extending through the mitral valve opening into the left atrium, and thereby preventing a condition which is commonly referred to as inversion of the leaflets, which results in mitral valve regurgitation.

However, weakening of the cords which connect the valve leaflets to the muscular wall of the heart, or rupturing of some of the cords results in excessive movement of the valve leaflets, thereby permitting inversion of the valve leaflets. In the closed state of a normal mitral valve, the valve leaflets extend directly from the valve

annulus into the left ventricle and abut each other for isolating the left ventricle from the left atrium. However, when excessive movement of the valve leaflets is permitted as a result of weakening or rupturing of the cords, a portion of one or both of the valve leaflets extends initially from the valve annulus into the left atrium before returning through the valve opening into the left ventricle, thus resulting in the condition known as inversion of the valve leaflets. Once one or both of the valve leaflets invert in the closed state, the leaflets fail to adequately abut each other, thus leading to partial failure of the mitral valve to isolate the left ventricle from the left atrium. This, thus, permits backflow of the pressurised blood from the left ventricle to the left atrium, thus resulting in mitral valve regurgitation. Inversion of the valve leaflets can also result from distortion of the valve annulus, where the valve annulus distorts from being circular to oval. Such distortions may result, for example, from distortion of the heart wall.

A number of procedures for repairing the mitral valve in the heart which avoid open heart surgery are known. One such procedure requires fastening the free ends of the valve leaflets together at a single point with a staple in order to limit the movement of the valve leaflets, and also to cause the valve leaflets to move together from the open to the closed state. Such a procedure is disclosed in U.S. Patent Specification No. 6,269,819 of Oz et al and in U.S. Patent Specification No. 6,312,447 of Grimes. However, while this procedure tends to limit the degree of inversion of the valve leaflets, in many cases, it does not completely eliminate inversion of the valve leaflets, and in cases where the cords connecting the valve leaflets to the muscular wall of the heart have been seriously weakened or where many of the cords have been ruptured, the reduction in inversion in many cases is minimal.

An alternative non-surgical procedure for repair of the mitral valve, where the inversion of the valve leaflets has resulted from distortion of the valve annulus, is to insert a circular ring in the tissue adjacent the valve annulus for correcting the distortion.

A further alternative procedure for repairing the mitral valve where the inversion of the valve leaflets has resulted from distortion of the valve is disclosed in U.S. Published Patent Application No. 2002/0095167 of Liddicoat et al. The procedure disclosed by Liddicoat requires reducing the area of the valve opening defined by the valve annulus. A plurality of circumferentially spaced apart staples are inserted into the valve leaflets adjacent the valve annulus. The staples are then coupled together with a ligature which is pulled tightly for reducing the circumference of the valve annulus, thereby reducing the area of the valve opening.

While these procedures to some extent correct for inversion of the valve leaflets, in general, they do not eliminate inversion of the valve leaflets, and thus, fail to adequately correct mitral valve regurgitation.

There is therefore a need for a device for correcting mitral valve regurgitation, and there is also a need for use of the device in the correction of mitral valve regurgitation. There is also a need for a device for correcting inversion of the leaflets of a leaflet valve in the heart.

The present invention is directed towards providing a device for correcting inversion of the leaflets of a leaflet valve in the heart, and the invention is also directed towards providing a device for correcting for mitral valve regurgitation, and the invention is also directed towards the use of the device in the correction of the inversion of leaflets of a leaflet valve in the heart, and use of the device for the correction of mitral valve regurgitation.

According to the invention there is provided a device for correcting inversion of a leaflet valve in the heart of a subject, wherein the device comprises an abutment means for locating in a cavity of the heart into which at least one of the leaflets inverts, the abutment means being provided for abutting the valve leaflets when the valve is in a closed state, and a retaining means co-operable with the heart and the abutment means for retaining the abutment means in abutting engagement with the valve leaflets when the valve is in the closed state for preventing inversion of the

valve leaflets.

In one embodiment of the invention the device is adapted for facilitating placement thereof in the heart of a subject through a catheter.

Advantageously, the device is adapted for facilitating placement thereof in the heart of a subject through a catheter inserted through the venous system of the subject.

Ideally, the device is collapsible into a collapsed state for facilitating catheter placement, and is erectable into an erect state on placement in the heart.

In one embodiment of the invention the device is resiliently erectable from the collapsed state to the erect state. Preferably, the device when in the collapsed state defines a relatively small transverse cross-sectional area for facilitating catheter placement in the heart.

In another embodiment of the invention the device is adapted for placement in the cavity of the heart through a catheter.

In a further embodiment of the invention the abutment means is adapted for locating adjacent the valve with a portion of the abutment means, which in use is to abut the valve leaflets of the valve lying adjacent a valve plane defined by the annulus of the valve for preventing the valve leaflets protruding through the valve plane into the cavity in which the device is located, for in turn preventing inversion of the valve leaflets.

Preferably, the abutment means is provided for extending across the valve, and advantageously, for extending diametrically across the valve. Ideally, the abutment means abuts the annulus of the valve.

In one embodiment of the invention the abutment means comprises at least one elongated abutment member.

In another embodiment of the invention the abutment means comprises at least two elongated abutment members extending transversely of each other.

Preferably, at least one of the elongated abutment members is adapted for extending across the valve and for abutting the annulus thereof at respective opposite sides of the valve. Advantageously, at least one of the elongated abutment members is adapted to abut the annulus of the valve on diametrically opposite sides thereof.

In one embodiment of the invention the retaining means extends from the abutment means and terminates in a wall engaging portion for engaging a portion of a wall of the heart for retaining the abutment means in abutting engagement with the valve leaflets when the valve leaflets are in the closed state.

In another embodiment of the invention the retaining means is provided by a cage-like structure extending from the abutment means.

In a further embodiment of the invention the retaining means and the abutment means together form a cage-like structure. Preferably, the cage-like structure is formed of wire. Advantageously, the wire forming the cage-like structure is a resilient wire for facilitating resilient erection of the device from the collapsed state to the erect state.

In one embodiment of the invention the wire is nickel titanium alloy.

In one embodiment of the invention at least a portion of the device is surface coated with a therapeutic agent.

In one embodiment of the invention the therapeutic agent is provided on the abutment means.

In another embodiment of the invention the therapeutic agent is provided on the retaining means.

In a further embodiment of the invention a means for absorbing a therapeutic agent and for subsequently slow releasing the therapeutic agent is provided on the device for facilitating slow release of the therapeutic agent therefrom into the bloodstream passing through the heart.

In one embodiment of the invention the means for absorbing the therapeutic agent is located on the abutment means.

In another embodiment of the invention the means for absorbing the therapeutic agent is located on the retaining means.

In a further embodiment of the invention the therapeutic agent is absorbed into the therapeutic absorbing means.

In one embodiment of the invention the therapeutic agent is an anti-clotting agent.

In another embodiment of the invention the therapeutic agent is an anti-coagulating agent.

In a further embodiment of the invention the therapeutic agent is suitable for dissolving blood clots.

In a still further embodiment of the invention the therapeutic agent is a preventative drug for preventing inflammation of tissue in contact therewith.

In another embodiment of the invention the therapeutic agent is an antibiotic.

In a further embodiment of the invention the therapeutic agent is an antiviral agent.

In a still further embodiment of the invention the therapeutic agent is an agent for use in gene therapy.

In one embodiment of the invention a sealing means is provided on the device for sealing a puncture in a wall of the heart defining a part of the cavity punctured during placement of the device in the cavity.

In another embodiment of the invention a locating means extends from the device for projecting into a wall of the heart defining a part of the cavity for securely locating the device in the cavity.

Preferably, the locating means is adapted for projecting through an opening in the heart wall, and a securing means is provided co-operating with the locating means for securely locating the device in the cavity.

Advantageously, the securing means co-operates with the locating means and the device for clamping the device to the heart wall.

In one embodiment of the invention the securing means is provided by the sealing means.

In another embodiment of the invention the securing means acts to seal the opening through which the locating means extends.

Advantageously, the sealing means is provided for sealing an opening in the heart wall which is formed for providing access to the cavity for placing the device therein.

In one embodiment of the invention the device is for correcting mitral valve regurgitation resulting from inversion of leaflets of the mitral valve, and the abutment means is for locating in the left atrium of the heart for abutting the valve leaflets when the mitral valve is in the closed state.

In one embodiment of the invention a closure means is provided on the device for closing off the left arterial appendage of the left atrium.

In another embodiment of the invention the closure means is located on the retaining means.

In a further embodiment of the invention the closure means is a patch type closure means.

In a further embodiment of the invention the closure means comprises a sleeve extending around the device.

In another embodiment of the invention the sleeve extends around the retaining means.

Preferably, the closure means is of fabric material. Alternatively, the closure means is of a polymer material.

The invention also provides a device for correcting mitral valve regurgitation in the heart of a subject resulting from inversion of the leaflets of the mitral valve, wherein the device comprises an abutment means for locating in the left atrium of the heart for abutting the valve leaflets when the mitral valve is in a closed state, and a retaining means co-operable with the heart and the abutment means for retaining the abutment means in abutting engagement with the valve leaflets when the mitral valve is in the closed state for preventing inversion of the valve leaflets.

The invention further provides a device according to the invention for use in the correction of a leaflet valve in the heart of a subject for preventing backflow through the valve when the valve is in the closed state.

The invention also provides a device according to the invention for use in the correction of the mitral valve in the heart of a subject for preventing mitral valve

regurgitation.

Additionally the invention provides a device for use in the correction of a leaflet valve in the heart of a subject for preventing backflow through the valve in the closed state, wherein the device comprises an abutment means for locating in a cavity of the heart into which at least one of the leaflets of the valve inverts for abutting the valve leaflets when the valve is in the closed state, and a retaining means co-operating with the heart and the abutment means for retaining the abutment means in abutting engagement with the valve leaflets when the valve is in the closed state for preventing inversion of the leaflets.

Further the invention provides a device for use in the correction of the mitral valve in the heart of a subject for preventing mitral valve regurgitation, wherein the device comprises an abutment means for locating in the left atrium of the heart for abutting the valve leaflets when the mitral valve is in a closed state, and a retaining means co-operable with the heart and the abutment means for retaining the abutment means in abutting engagement with the valve leaflets when the mitral valve is in the closed state for preventing inversion of the valve leaflets.

The invention also provides use of the device according to the invention for correcting inversion of the leaflets of a leaflet valve in the heart of a subject.

The invention also provides use of the device according to the invention for correcting for mitral valve regurgitation in the heart of a subject.

The advantages of the invention are many. The device according to the invention substantially eliminates inversion of the valve leaflets, and in general, completely eliminates inversion of the valve leaflets. By eliminating inversion of the valve leaflets, backflow through the valve when the valve is in the closed state is avoided. When the device is located in the left atrium of the heart for correcting inversion of the mitral valve, mitral valve regurgitation in most cases is completely corrected. By virtue of the fact that the device comprises an abutment means for engaging the

valve leaflets in the closed state, the abutment means prevents the valve leaflets extending into the cavity in which the device is located, thereby preventing inversion of the valve leaflets. Thus, when the device is located in the left atrium, inversion of the valve leaflets of the mitral valve into the left atrium is prevented. The provision of the retaining means for co-operating with the heart and the abutment means ensures that the abutment means is located for engaging the valve leaflets when the valve leaflets are urged into the closed state, thereby preventing inversion of the valve leaflets.

A particularly important advantage of the invention is achieved when the abutment means is provided by abutment members which extend across the valve opening adjacent the valve plane defined by the valve, since once the abutment members are located adjacent the valve plane for abutting the valve leaflets, the valve leaflets are prevented from transitioning across the valve plane into the cavity in which the device is located, and when the device is located in the left atrium for correcting inversion of the leaflets of the mitral valve, transitioning of the valve leaflets across the valve plane from the left ventricle into the left atrium is prevented, thus ensuring inversion of the valve leaflets is avoided.

Another particularly important advantage of the invention is achieved when the device is provided to be collapsible into a collapsed state, since once the device is collapsed into the collapsed state, it can be readily directed into the cavity of the heart in which it is to be located through a catheter extending through the venous system of the subject for facilitating placement of the device in the cavity. The provision of the device as being resiliently erectable from the collapsed state to the erect state provides a particularly important advantage, in that once the device has been deposited through a catheter into the cavity of the heart, on being discharged from the catheter, the device erects itself from the collapsed state into the erect state due to its inherent resilience.

The provision of the device in the form of a cage structure which incorporates the retaining means and the abutment means has the particular advantage that the

device can be shaped and sized to snugly fit within the cavity of the heart in which it is to be located, thereby minimising any resistance which the device may cause to blood flow. When the device is located in the left atrium, the fact that the device is in the form of a cage like structure minimises any resistance to blood flow through the left atrium. Additionally, by providing the cage structure of a resilient material the cage structure is readily resiliently erectable from the collapsed state to the erect state when discharged from the catheter into the cavity of the heart, such as the left atrium.

Providing a coating of a therapeutic agent on the abutment means, and/or also on the retaining means has the advantage that a therapeutic agent can be readily administered to the subject as the blood flows past the device. By providing the device with a means for absorbing a therapeutic agent, which permits slow release of the therapeutic agent, has the added advantage that sustained administration of the therapeutic agent to a subject can be achieved. The therapeutic agent which may be coated on the device or provided in the means for absorbing the therapeutic agent may include any type of therapeutic agent, whether it be an anti-clotting agent, an anti-coagulating agent, an antibiotic, an antiviral agent or any other appropriate type of drug, therapeutic or other agent.

The advantage of providing a closure means for closing off the left arterial appendage of the left atrium has the advantage of reducing the propagation of blood clots, which can lead to strokes and other complications. The left arterial appendage of the left atrium is known to be a source of blood clots.

By providing the device with a locating means for projecting into a wall of the heart, the device can be securely and positively located in the cavity of the heart in which the device is located, and thus, can be securely and positively located relative to the valve, the leaflet inversion of which is to be corrected. By providing the locating means for projecting through an opening in the heart wall, particularly positive and secure location of the device in the cavity of the heart is achieved. A further advantage of providing the locating means for projecting through an opening in the

heart wall is that the locating means can be located in an opening formed in the heart wall for facilitating catheter placement of the device in the cavity, and the securing means for securing the locating means to the heart wall can be provided as a sealing means for sealing the opening. This is particularly advantageous when the device is used for correcting mitral valve regurgitation, since catheter placement of the device in the left atrium would typically be achieved by puncturing the septum which separates the left atrium from the right atrium, and thus, the device can be secured in the puncture opening, and the sealing means of the securing means would thus seal the puncture opening.

Additionally, the advantage of providing a sealing means on the device for sealing a puncture opening would have similar advantages, in that a puncture opening formed for facilitating catheter placement of the device in the cavity of the heart could readily be sealed by the sealing means.

The invention will be more clearly understood from the following description of some preferred embodiments thereof, which are given by way of example only, with reference to the accompanying drawings, in which:

Fig. 1 is a perspective view of a device according to the invention for correcting mitral valve regurgitation in the heart of a subject,

Fig. 2 is a perspective view of the device of Fig. 1 illustrated in a portion of a catheter for catheter placement in the heart,

Fig. 3 is a perspective view of the device of Fig. 1 also illustrated in a portion of a catheter for catheter placement in the heart,

Fig. 4 is a transverse cross-sectional elevational view of the heart of a subject illustrating the device of Fig. 1 in use,

Fig. 5 is a transverse cross-sectional elevational view of the heart of a subject

also illustrating the device of Fig. 1 in use,

Fig. 6 is a transverse cross-sectional view of the heart illustrating inversion of the leaflets of the mitral valve in the closed state,

Fig. 7 is a perspective view of a device according to another embodiment of the invention also for correcting mitral valve regurgitation,

Fig. 8 is a perspective view of a device according to another embodiment of the invention also for correcting mitral valve regurgitation,

Fig. 9 is a view similar to Fig. 5 illustrating the device of Fig. 8 in use,

Fig. 10 is a front elevational view of a device according to another embodiment of the invention also for correcting mitral valve regurgitation,

Fig. 11 is a front elevational view of a detail of the device of Fig. 8,

Fig. 12 is a front elevational view of an alternative form of the detail of Fig. 10 of the device of Fig. 8,

Fig. 13 is a perspective view of a device according to another embodiment of the invention also for correcting mitral valve regurgitation,

Fig. 14 is a front elevational view of a device according to another embodiment of the invention also for correcting mitral valve regurgitation,

Fig. 15 is a perspective view of a device according to a further embodiment of the invention also for correcting mitral valve regurgitation,

Fig. 16 is a perspective view of a device according to a further embodiment of the invention also for correcting mitral valve regurgitation,

Fig. 17 is a perspective view of a device according to a still further embodiment of the invention also for correcting mitral valve regurgitation,

Fig. 18 is a perspective view of a device according to a still further embodiment of the invention also for correcting mitral valve regurgitation,

Fig. 19 is a side elevational view of the device of Fig. 18,

Fig. 20 is a side elevational view of the device of Fig. 18 in use, and

Fig. 21 is a side elevational view of a device according to a still further embodiment of the invention for correcting mitral valve regurgitation.

Referring to the drawings and initially to Figs. 1 to 5, there is illustrated a device according to the invention, indicated generally by the reference numeral 1, for locating in a cavity of the heart for preventing inversion of the leaflets of a leaflet valve of the heart, in this case the device 1 is particularly suitable for correcting mitral valve regurgitation in the heart 2 of a subject resulting from inversion of the leaflets 3 of the mitral valve 4. The device 1 is suitable for placement in the heart 2 through a catheter 5, thereby avoiding the need for open heart surgery for correcting the mitral valve 4.

Before describing the device 1 in detail, the relevant portion of the heart of a subject will first be described with reference to Figs. 4 to 6. The heart 2 comprises, inter alia, a left ventricle 6 and a left atrium 7. Blood returning from the lungs enters the heart through the left atrium 7, and flows passively through the mitral valve 4 from the left atrium 7 to the left ventricle 6, from which it is pumped by the pumping action of the heart wall through the aorta 9 into the arterial system of the subject. The mitral valve 4 is located between the left atrium 7 and the left ventricle 6, and comprises an annulus 10 which is normally circular, and which defines a circular valve opening 11 through which the left atrium 7 communicates with the left ventricle

6. The annulus 10 also defines a valve plane 12 in which the valve opening 11 lies.

The two valve leaflets 3 extend from the annulus 10 into the left ventricle 6, and cords 15 connect the free ends of the valve leaflets 3 to the muscular wall 16 of the heart 2 for retaining the leaflets 3 in an open state, as illustrated in Fig. 4, for permitting passive blood flow from the left atrium 7 to the left ventricle 6. The cords 15 also constrain the valve leaflets 3 to move together from the open state to a closed state, which is illustrated in Figs. 5 and 6. The valve leaflets 3 are passive valve members, and contractions of the heart for pumping blood from the left ventricle 6 through the aorta 9 cause the valve leaflets 3 to adopt the closed state.

In the closed state, when the valve leaflets 3 correctly abut each other, backflow of blood from the left ventricle 6 to the left atrium 7 is prevented, thereby preventing mitral valve regurgitation. However, weakening or severing of the cords 15 results in inversion of the valve leaflets 3 in the closed state, which results in one or both of the valve leaflets protruding into the left atrium 7 as illustrated in Fig. 6, which is the condition discussed above, which is commonly referred to as inversion of the valve leaflets. Distortion of the annulus 10 from circular to, for example, oval shape, as discussed above, also leads to inversion of the valve leaflets. The device 1 according to the invention is provided for correcting inversion of the valve leaflets 3, and in turn for preventing mitral valve regurgitation, or at least significantly reducing mitral valve regurgitation.

Referring now in particular to Figs. 1 to 5, the device 1 will now be described in detail. The device 1 is constructed in the form of a wire cage 20 from wire of nickel titanium alloy of the type commonly referred to as super-elastic or memory wire. By forming the device 1 as a wire cage 20 from the nickel titanium alloy wire, once the cage 20 is formed and appropriately heat treated, the cage 20 may be squeezed or urged into a collapsed state, as illustrated in Figs. 2 and 3, and on release, the cage 20 resiliently returns to its original erect state. Thus, by forming the device 1 as a wire cage 20 of nickel titanium alloy wire, the device 1 is suitable for placement in the heart 2 through the catheter 5. In this embodiment of the invention the wire cage

20 is of circular transverse cross-section, and may be of a suitable diameter, typically, in the range of 0.007mm to 0.08mm. However, it will be appreciated that the wire may be of any other suitable transverse cross-section, for example, square, rectangular, flat, polygonal or indeed, any other transverse cross-section.

The cage 20 comprises an abutment means, in this embodiment of the invention a pair of elongated abutment members 21, which extend transversely of each other for locating adjacent and substantially in the valve plane 12 of the mitral valve 4 for abutting the valve leaflets 3 of the mitral valve 4, when the valve leaflets 3 are in the closed state for preventing the leaflets 3 projecting into the left atrium 7 through the valve plane 12, and thus preventing inversion of the valve leaflets 3. A retaining means formed by four elongated retaining members 23, which extend from the ends of the abutment members 21 terminate in a wall engaging portion 24 for engaging an inner upper portion 25 of the wall 16 of the heart 2 in the left atrium 7, and for co-operating with the wall 16 and the abutment members 21, for in turn retaining the abutment members 21 substantially in the valve plane 12 of the mitral valve 4.

The abutment members 21 are of length substantially corresponding to the diameter of the annulus 10 of the mitral valve 4, so that in use the abutment members 21 abut and are urged against the annulus 10 and extend diametrically across the valve opening 11, and thus abut the valve leaflets 3 in the closed state. The length of the retaining members 23 is such as to span the left atrium 7 so that when the engagement portion 24 is in engagement with the upper portion 25 of the wall 16 of the heart 2, the abutment members 21 are located abutting and urged against the annulus 10, adjacent and substantially in the valve plane 12 of the mitral valve 4.

In this embodiment of the invention the cage 20 is formed of four pieces of nickel titanium alloy welded together at 24 and 26, and each are bent at 27 for forming the respective abutment member 21 and retaining member 23. After welding of the four pieces of wire together at 24 and 26 to form the cage 20, the cage 20 is heat treated for imparting memory to the cage 20, so that when it is collapsed into the collapsed state for catheter placement, on being discharged from the catheter 5, the cage 20

resiliently self-erects to its original erect state.

The cage 20 in this embodiment of the invention can be collapsed into the collapsed state into a relatively elongated shape of relatively small transverse cross-sectional area as illustrated in Fig. 2, and is thus suitable for passing through the catheter 5 for placement in the left atrium 7. In this embodiment of the invention the cage 20 can be collapsed to have a transverse cross-sectional diameter of approximately 6mm, which is ideally suited for passing through a catheter.

Referring now to Figs. 2 and 3, the catheter for placing the device 1 in the left atrium may be any suitable catheter of the type which will be well known to those skilled in the art commonly used for placing surgical implants at remote sites in the body of a subject, and in particular, in the heart of a subject. The device 1 is carried on the end of a control wire 28, which urges the device 1 through the catheter 5. The control wire 28 facilitates manipulating and positioning the device 1 in the left atrium as it is being passed out of the catheter 5 into the left atrium 7. A suitable remotely operated release mechanism (not shown) is provided at the end of the control wire 28 for detaching the device 1 from the control wire 28 when the device 1 has been correctly located and placed in the left atrium. A control mechanism (not shown) is provided at the other end of the control wire 28 for facilitating operation of the release mechanism (not shown) for releasing the device 1 from the control wire 28.

In use, the catheter 5 is passed through the venous system of the subject and into the left atrium 7. Typically, the catheter 5 is passed through the inferior or superior vena cavac to the right atrium of the heart. The septum separating the left and right atria is punctured, and the catheter 5 is then passed through the punctured septum from the right atrium into the left atrium 7. This type of procedure for accessing the left atrium of the heart will be well known to those skilled in the art, since it is a commonly used procedure in valvuloplasty procedures.

When the catheter 5 is appropriately positioned in the left atrium 7, the device 1 is attached to the control wire 28 which is then urged through the catheter 5, for in turn

urging the device 1 through the catheter 5 into the left atrium 7. Prior to being delivered into the left atrium 7, the device 1 is oriented within the catheter 5 by the control wire 28, so that the device 1 will be correctly oriented when discharged into the left atrium 7 from the catheter 5. Once correctly oriented, the device 1 is discharged from the catheter 5 into the left atrium 7 by the control wire 28. On discharge from the catheter 5 the device 1 self erects from the collapsed state into the erect state under its own inherent resilience. The device 1 is then finally positioned in the left atrium 7 with the abutment members 21 abutting the annulus 10, and extending diametrically across the valve opening 11 adjacent and substantially in the valve plane 12. Once the device 1 is so positioned, the engagement portion 24 abuts the portion 25 of the wall 16 of the heart 2. The release mechanism (not shown) is then operated and the device 1 is released from the control wire 28, and the catheter 5 and control wire 28 are withdrawn from the subject.

The orientation and manipulation of the device 1 in the left atrium 7 is observed on a visual display unit (not shown) by appropriately imaging the device 1 when in the left atrium 7 by any suitable imaging means, for example, X-ray, ultrasonic or other suitable imaging means. With the device 1 correctly positioned in the left atrium 7 with the abutment members 21 abutting the annulus 10 and extending diametrically across the valve opening 11 adjacent and substantially in the valve plane 12, and the engagement portion 24 abutting the portion 25 of the heart wall 16, as the valve leaflets 3 are urged into the closed state by the pumping action of the heart, the valve leaflets 3 abut the abutment members 21, which thus prevent the valve leaflets 3 projecting through the valve plane 12 into the left atrium 7, thus avoiding inversion of the valve leaflets 3, and in turn preventing mitral valve regurgitation.

Referring now to Fig. 7, there is illustrated a device according to another embodiment of the invention, indicated generally by the reference numeral 30, also for correcting mitral valve regurgitation. The device 30 is constructed from nickel titanium alloy and is substantially similar to the device 1, and similar components are identified by the same reference numerals. The main difference between the device

30 and the device 1 is in the arrangement of the abutment member. In this embodiment of the invention the retaining members 23 terminate in an annulus engaging ring 33 for engaging the annulus 10 of the mitral valve 4 for in turn facilitating location of the device 30 concentrically with the annulus 10. One main abutment member 31 extends diametrically across the annulus engaging ring 33 between two of the retaining members 23, and four secondary abutment members 32 extend from the annulus engaging ring 33 between adjacent retaining members 23.

Otherwise, the device 30 is similar to the device 1, and is suitable for catheter placement in the left atrium 7 as already described with reference to the device 1.

Referring now to Figs. 8 and 9, there is illustrated a device according to another embodiment of the invention, indicated generally by the reference numeral 40, for correcting mitral valve regurgitation. The device 40 is also of cage construction comprising a cage structure 41. However, in this embodiment of the invention the cage structure 41 substantially defines a sphere. The cage structure 41 is formed by a plurality of hoops 42 of nickel titanium alloy wire, some of which extend parallel to each other and others transversely of each other. The hoops 42 are arranged so that when any portion 43 of the cage structure 41 is located adjacent the mitral valve 4, portions 44 of the hoops 42 form abutment members, which abut the annulus 10 of the mitral valve 4, and extend transversely across the valve opening 11 substantially in the plane 12 of the mitral valve 4. Additionally, the cage structure 41 is of size such that when located in the left atrium 7 with the portion 43 adjacent the mitral valve 4, a portion 46 of the cage structure 41 diametrically opposite the portion 43 located adjacent the mitral valve 4 abuts the upper portion 25 of the wall 16 of the heart 2, for in turn urging the portion 43 of the cage structure 41 into engagement with the mitral valve 4 for abutting the valve leaflets 3 in the closed state, for in turn preventing projection of the valve leaflets 3 through the valve plane 12 into the left atrium 7.

The hoops 42 are joined together by any suitable joining means, for example,

bonding, brazing, welding or the like.

Additionally, the cage structure 41 of the device 40 is constructed in order to be collapsible into an elongated shape of relatively small transverse cross-sectional area for facilitating catheter placement in the left atrium 7.

Referring now to Figs. 10 to 12, there is illustrated a device according to another embodiment of the invention, indicated generally by the reference numeral 50, for correcting mitral valve regurgitation. The device 50 is substantially similar to the device 40, and comprises a spherical cage structure 51, which in this embodiment of the invention is formed by a plurality of cords 52, which are formed by a plurality of polygonal loops of nickel titanium alloy wire, which are joined together to define a sphere.

The cords 52 of the cage structure 51 are arranged so that irrespective of how the device 50 is located in the left atrium 7, a portion 53 of the cage structure 51, which is adjacent the mitral valve 4 presents portions 54 of the cords 52 which act as abutment members for abutting the annulus 10 of the mitral valve 4. Additionally, the spacing of the cords 52 is such that irrespective of the orientation of the device 50 in the left atrium 7, a sufficient number of the cords 52 extend across the valve opening 11 of the mitral valve 4 adjacent the valve plane 12 for abutting the valve leaflets 3 in the closed state for preventing the valve leaflets 14 projecting through the valve plane 12 into the left atrium 7. The cage structure 51 is sized so that when any portion 53 is adjacent the mitral valve 4, a diametrically opposite portion 56 abuts the upper portion 25 of the heart wall 16 in the left atrium 7 for in turn urging and retaining the portion 53 in engagement with the mitral valve 4.

The polygonal loop forming the cords 52 may be joined together by any suitable method, for example, by intertwining as illustrated in Fig. 11, by bonding as illustrated in Fig. 12, or by welding or brazing or by any other suitable means.

Otherwise the device 50 is similar to the device 40, and is suitable for catheter

placement in the left atrium 7.

Referring now to Fig. 13, there is illustrated a device according to a further embodiment of the invention, indicated generally by the reference numeral 60, for correcting mitral valve regurgitation. The device 60 is substantially similar to the device 40. The device 60 comprises a cage structure of nickel titanium alloy wire, and is also suitable for catheter placement in the left atrium 7 in similar fashion as the device 40.

Fig. 14 illustrates another alternative construction of device, namely, a device 70 for correcting mitral valve regurgitation. The device 70 is of cage construction, and is constructed from nickel titanium alloy wire. The device 70 is substantially similar to the device 40. The device 70 is collapsible from an erect state to a collapsed state, and is resiliently erectable into the erect state, and is thus suitable for catheter placement in the left atrium.

Referring now to Fig. 15, there is illustrated a device according to another embodiment of the invention, indicated generally by the reference numeral 80, also for correcting mitral valve regurgitation. The device 80 comprises a cage 81 of wire 82, which substantially defines a sphere, and is somewhat similar to the device 40 described with reference to Figs. 8 and 9. The wire 82 forming the cage 81 is nickel titanium alloy wire of circular transverse cross-section of approximately 0.075mm diameter. However, in this embodiment of the invention the cage 81 is formed from one single length of the wire 82 which is shaped to define the sphere, and portions of the wire 82 where the wire crosses over itself are joined together by solder joints 84, and portions 85 extending between the respective joints 84 form arcuate segments which together define the sphere. In forming the cage 81, the wire 82 in this embodiment of the invention is wound onto a former (not shown) which locates the wire in the appropriate pattern to form the cage 81. When the wire 82 is formed onto the former, the wire 82 is subjected to heat treatment in order to impart memory to the wire when formed into the cage 81. After heat treatment the portions where the wire crosses over itself are tied with wire thread, and then soldered to form the joints

84. The former (not shown) is then collapsed and removed.

The device 80 is collapsible into a collapsed state, and is self resiliently erectable to its normal erect state, and thus, is suitable for catheter placement in the left atrium of the heart.

Referring now to Fig. 16, there is illustrated a device according to a further embodiment of the invention, indicated generally by the reference numeral 90, also for correcting mitral valve regurgitation. The device 90 is substantially similar to the device 40, and comprises a spherical cage structure 91 of nickel titanium alloy wire, and is thus suitable for catheter placement in the left atrium 7. However, in this embodiment of the invention as well as being suitable for correcting mitral valve regurgitation, the device 90 also acts to reduce the propagation of blood clots leading to strokes. The device 90 comprises a closure means, in this embodiment of the invention provided by a patch 92 which is provided to close off a pouch-like part of the left atrium, which is referred to as the left arterial appendage, which is associated with the propagation of blood clots leading to strokes. In this embodiment of the invention when the device is located in the left atrium, it is oriented so that the patch 92 closes off the left arterial appendage. Otherwise, the device 90 is similar to the device 40. The patch 92 may be of any suitable material such as a woven fabric material or a polymer film material.

Referring now to Fig. 17, there is illustrated a device according to a still further embodiment of the invention, indicated generally by the reference numeral 95, also for correcting mitral valve regurgitation. The device 95 is substantially similar to the device 90. The only difference between the device 95 and the device 90 is that instead of the closure means being provided by a patch as is the case with the device 90, the closure means is provided by a sleeve 96 which extends around the device 95 for closing off the left arterial appendage. The sleeve 96 may be of any suitable material, for example, a fabric or polymer film.

Otherwise the device 95 is similar to the device 90, and similar components are

identified by the same reference numerals.

Referring now to Figs. 18 to 20, there is illustrated a device according to a still further embodiment of the invention, indicated generally by the reference numeral 100, for preventing inversion of the leaflets of the mitral valve 4 of the heart 2, for in turn preventing mitral valve regurgitation. The device 100 comprises a cage 101 which substantially defines a sphere, and is formed by a plurality of circular loops 102 of wire of nickel titanium alloy. The loops 102 are joined by solder joints 103. In this embodiment of the invention the device 100 comprises a locating means for securely and positively locating the device 100 in the left atrium 7 of the heart. The locating means is formed by a main joint 105 by which a securing means formed by a sealing member 106 is secured to the cage 101. The sealing member 106 is of a polymer film material, and is secured to the cage 101 by the main joint 105 which is formed by adhesive, solder or brazing, as will be described below. The main joint 105 is provided for engaging in an opening 107 formed in the septum 108 which separates the left atrium 7 from the right atrium 109, a portion of which is also illustrated in Fig. 20, of the heart. The opening 107 is formed in the septum for providing access to the left atrium 7 from the right atrium 109 for catheter placement of the device 100 in the left atrium 7. The sealing member 106 co-operates with the cage 101 for clamping the device 100 onto the septum 108. Additionally, the sealing member 106 acts as a sealing means for sealing the opening 107 formed in the septum 108.

The sealing member 106 is reinforced by a pair of wires 112 which extend transversely relative to each other for maintaining the sealing member 106 to form a plate like configuration. The pair of wires 112 are secured to the cage 101 by the main joint 105, which as discussed above may be either an adhesive joint, a solder joint, a brazed joint, a welded joint or any other suitable joint. However, the wires 112 are similarly heat treated, as is the cage 101 to be collapsible for facilitating catheter placement of the device 100 in the left atrium 7, and to be resiliently self-erectable from a collapsed state into the erect plate like configuration state of Figs. 18 to 20 for securing and sealing the device 100 in the septum 108.

The loops 102 are arranged so that segments 110 of two of the loops 102 form abutment members 21 for abutting the annulus 10 of the mitral valve 4, and extending transversely across the mitral valve 4 adjacent the valve plane 12 for in turn abutting the leaflets 3 of the mitral valve 4, when the mitral valve 4 is in the closed state, for preventing inversion of the leaflets 3 and in turn preventing mitral valve regurgitation.

In use, the device 100 is placed in the atrium 7 by a catheter, similar to the catheter 5. The opening 107 is formed in the septum 108, and the catheter 5 is passed through the opening 107 from the right atrium 109 to the left atrium 7. The device 100 in the collapsed state is then passed through the catheter 5 and entered into the left atrium 7. However, before the sealing member 106 is discharged from the catheter, the catheter is withdrawn into the right atrium 109, and the device 100 is then released from the catheter. On release, the sealing member 106 resiliently erects into its plate like configuration illustrated in Figs. 18 to 20, thereby clamping the device 100 in the septum 108, and sealing the opening 107 in the septum 108.

The opening 107 is formed at a position in the septum 108 so that when the device 100 is located in the left atrium 7 and clamped to the septum 108, the segments 110 of two of the loops 102 abut and are urged into engagement with the annulus 10 of the mitral valve 4 so that the segments 110 extend transversely across the mitral valve 4 adjacent the valve plane 12. Thus, the device 100 is securely and positively located in the left atrium 7 by the co-operating clamping action between the sealing member 106 and the cage 101.

Referring now to Fig. 21, there is illustrated a device according to a still further embodiment of the invention, indicated generally by the reference numeral 120, also for preventing inversion of the leaflets of the mitral valve of the heart, for in turn preventing mitral valve regurgitation. The device 120 is substantially similar to the device 1 of Figs. 1 to 5, and similar components are identified by the same reference numerals. The only difference between the device 120 and the device 1 is that a ring 121 of nickel titanium alloy wire is secured by solder joints 122 to the retaining

members 23 for locating the retaining members 23 spaced apart around the ring 121 at 90° intervals, for in turn retaining the abutment members 21 extending transversely relative to each other. The device 120 is likewise suitable for catheter placement in the left atrium of the heart.

While the devices according to the invention have been described for correcting inversion of the leaflets of the mitral valve for preventing mitral valve regurgitation, it is envisaged that the devices according to the invention may be used for correcting inversion in the leaflets of any leaflet valve of the heart. In which case, the device would be located in a cavity of the heart into which the leaflets of the valve invert for preventing inversion thereof, in similar fashion as inversion of the leaflets of the mitral valve is prevented.

It is also envisaged that the devices according to the invention which have been formed as cage structures may be formed so that the cage structure is stiffer in some regions than in others. In which case, the less stiff regions would be more compliant than the stiff regions, and would be suitable for locating adjacent the heart wall for accommodating movement of the heart wall. This would thus allow the chamber within which the device is located to contract during the pumping action of the heart. The stiffer and less stiff regions could be formed by appropriately patterning the wire of the cage structures, and/or by forming the portions which are to be less stiff with wire of smaller transverse cross-section.

Additionally, it is envisaged that the heat treatment of the cages may be carried out in a manner which provides different portions of the cage structures with different properties, for example, the heat treatment may be carried out in such a way that portions of the cage structure are of more or less resilient strength than other portions of the cage structure.

By appropriately altering the stiffness of the cage from one region to another, the stiffness could be arranged in certain areas for facilitating movement of a region of the cage with movement of the heart wall, as the heart wall pumps blood through the

heart. In other words, the less stiff region or regions could be located adjacent muscular walls of the heart, and the less stiff region or regions could move simultaneously with the heart wall during pumping.

While the wire or wires forming the cage structures of the devices according to the invention have been described as being joined by solder joints, the wires may be brazed or welded to form the joints, or may be bonded to form the joints. It is also envisaged in certain cases that the joints of the wire or wires may be made by merely tying the portions of the wires together where the wires cross over each other or run parallel to each other with, for example, steel wires. Alternatively, the wires may be joined by knotting the wires together. It is also envisaged that the wire or wires may be joined by laser welding or any other suitable welding or soldering. An advantage of forming the joints by soldering is that the joints are X-ray opaque, thus forming markers for imaging of the device as it is being passed through the catheter, and also as it is being arranged in and located in the left atrium or other cavity of the heart.

It is envisaged that in each of the devices according to the invention for correcting mitral valve regurgitation, the components of the devices, in particular, the nickel titanium alloy wire, may be surface coated with a therapeutic agent. It is also envisaged in certain cases that the devices according to the invention for correcting mitral valve regurgitation may be provided with a means for absorbing a therapeutic agent. Such a means for absorbing a therapeutic agent would typically comprise a coating of a slow release material with the therapeutic agent embedded therein coated onto the wire forming the devices, and the slow release material of the coating would facilitate slow release of the therapeutic agent into the blood as it passed through the heart. The therapeutic agent, whether coated onto the wire of the devices or absorbed into a slow release coating on the wire, may be provided for any appropriate therapeutic purpose, for example, the therapeutic agent may be a drug for preventing the formation of blood clots or for dissolving blood clots, or a drug for preventing inflammation of tissue of the heart in contact with the device, or a drug for curing an infection, or for any other appropriate purpose. Indeed, the

therapeutic agent may be an agent for gene therapy.

Indeed, where the wire of the devices is coated with a therapeutic agent, or absorbed in a slow release material coated onto the wire of the devices, if the therapeutic agent were provided as an anticoagulant, it is envisaged that with the devices so coated, there would be no need for providing the device with a patch or a sleeve for closing the left arterial appendage of the heart.

It is also envisaged that any of the devices according to the invention may be provided with a patch or other sealing means located in an appropriate position on the devices so that when the devices are finally oriented in the left atrium, the patch aligns with the puncture in the septum separating the left and right atria for in turn closing and sealing the puncture. Such a patch or other sealing means could be provided by a patch similar to the patch 92 of the device 90 but located at an appropriate position to be adjacent the puncture in the septum when the device is finally and appropriately oriented in the left atrium for preventing inversion of the valve leaflets. It is also envisaged that any other suitable sealing means and/or securing means may be provided on the device 100 described with reference to Figs. 18 to 20, or indeed, on any of the other devices described for securing and sealing the device in an opening through the septum, or indeed any other wall of the heart, from one cavity to another which is formed for facilitating catheter placement of the device in the cavity into which the device is to be located.

While specific shapes and constructions of the devices according to the invention have been described, the devices according to the invention may be provided in other suitable shapes and of other suitable construction without departing from the scope of the invention.

Additionally, while the devices according to the invention have been described as being constructed of nickel titanium wire, the devices may be constructed of any other suitable material which would facilitate collapsing and resilient re-erection of the devices. Indeed, in certain cases, it is envisaged that the devices instead of

being resiliently erectable when located in the left atrium, may be mechanically erectable by, for example, a pull string or the like extending through the catheter. In which case, it is envisaged that the abutment members and the retaining members will be appropriately connected together for facilitating collapsing and erection of the device. For example, the abutment members and the retaining members may be pivotally connected, and suitable locking means may be provided such that when operated into the erect state, the device would be retained by the locking means in the erect state. Such locking means may, for example, be provided by inter-engageable complementary formations formed on the respective abutment and retaining members.

It is also envisaged that the devices according to the invention may be provided so that the wire or wires of each device would conduct electrical signals for sensing, or exciting the electrical pathways in the heart, and in which case, a suitable communicating arrangement would be provided for communicating signals to and from the device, such a communicating means may be provided by radio communication or other suitable remote communication methods, or the device may be hardwired via the coronary sinus.

It is also envisaged that any or all of the devices according to the invention may be so shaped to define the normal shape of the cavity of a healthy heart into which the device is to be placed. In such cases, the advantage of such a device, particularly where the device is formed as a cage structure, would be to correct a distortion or deformity in the heart resulting from disease or other causes, and if such deformity or distortion of the heart resulted in distortion of the valve, the inversion of the leaflets of which is being corrected by the device, the fact that the device corrected the distortion or deformation in the heart would assist in correcting the distortion of the valve, which would further assist in correcting the inversion of the valve leaflets.

It is envisaged that the locating means which has been described in the device with reference to Figs. 18 to 20 as being provided by the main joint by which the sealing means is secured to the device may also form the retaining means for retaining the

abutment means adjacent the valve leaflets in the closed state.

Claims

1. A device for correcting inversion of a leaflet valve in the heart of a subject, characterised in that the device comprises an abutment means for locating in a cavity of the heart into which at least one of the leaflets inverts, the abutment means being provided for abutting the valve leaflets when the valve is in a closed state, and a retaining means co-operable with the heart and the abutment means for retaining the abutment means in abutting engagement with the valve leaflets when the valve is in the closed state for preventing inversion of the valve leaflets.

2. A device as claimed in Claim 1 characterised in that the device is adapted for facilitating placement thereof in the heart of a subject through a catheter.

3. A device as claimed in Claim 2 characterised in that the device is adapted for facilitating placement thereof in the heart of a subject through a catheter inserted through the venous system of the subject.

4. A device as claimed in Claim 2 or 3 characterised in that the device is collapsible into a collapsed state for facilitating catheter placement, and is erectable into an erect state on placement in the heart.

5. A device as claimed in Claim 4 characterised in that the device is resiliently erectable from the collapsed state to the erect state.

6. A device as claimed in Claim 4 or 5 characterised in that the device when in the collapsed state defines a relatively small transverse cross-sectional area for facilitating catheter placement in the heart.

7. A device as claimed in any of Claims 2 to 6 characterised in that the device is adapted for placement in the cavity of the heart through a catheter.

8. A device as claimed in any preceding claim characterised in that the abutment means is adapted for locating adjacent the valve with a portion of the

abutment means, which in use is to abut the valve leaflets of the valve lying adjacent a valve plane defined by the annulus of the valve for preventing the valve leaflets protruding through the valve plane into the cavity in which the device is located, for in turn preventing inversion of the valve leaflets.

9. A device as claimed in any preceding claim characterised in that the abutment means is provided for extending across the valve.

10. A device as claimed in Claim 9 characterised in that the abutment means is provided for extending diametrically across the valve.

11. A device as claimed in any preceding claim characterised in that the abutment means abuts the annulus of the valve.

12. A device as claimed in any preceding claim characterised in that the abutment means comprises at least one elongated abutment member.

13. A device as claimed in Claim 12 characterised in that the abutment means comprises at least two elongated abutment members extending transversely of each other.

14. A device as claimed in Claim 12 or 13 characterised in that at least one of the elongated abutment members is adapted for extending across the valve and for abutting the annulus thereof at respective opposite sides of the valve.

15. A device as claimed in any of Claims 12 to 14 characterised in that at least one of the elongated abutment members is adapted to abut the annulus of the valve on diametrically opposite sides thereof.

16. A device as claimed in any preceding claim characterised in that the retaining means extends from the abutment means and terminates in a wall engaging portion for engaging a portion of a wall of the heart for retaining the abutment means in

abutting engagement with the valve leaflets when the valve leaflets are in the closed state.

17. A device as claimed in any preceding claim characterised in that the retaining means is provided by a cage-like structure extending from the abutment means.

18. A device as claimed in Claim 17 characterised in that the retaining means and the abutment means together form a cage-like structure.

19. A device as claimed in Claim 17 or 18 characterised in that the cage-like structure is formed of wire.

20. A device as claimed in Claim 19 characterised in that the wire forming the cage-like structure is a resilient wire for facilitating resilient erection of the device from the collapsed state to the erect state.

21. A device as claimed in Claim 19 or 20 characterised in that the wire is of a nickel titanium alloy.

22. A device as claimed in any preceding claim characterised in that at least a portion of the device is surface coated with a therapeutic agent.

23. A device as claimed in Claim 22 characterised in that the therapeutic agent is provided on the abutment means.

24. A device as claimed in Claim 22 or 23 characterised in that the therapeutic agent is provided on the retaining means.

25. A device as claimed in any preceding claim characterised in that a means for absorbing a therapeutic agent and for subsequently slow releasing the therapeutic agent is provided on the device for facilitating slow release of the therapeutic agent therefrom into the bloodstream passing through the heart.

26. A device as claimed in Claim 25 characterised in that the means for absorbing the therapeutic agent is located on the abutment means.

27. A device as claimed in Claim 25 or 26 characterised in that the means for absorbing the therapeutic agent is located on the retaining means.

28. A device as claimed in any of Claims 25 to 27 characterised in that the therapeutic agent is absorbed into the therapeutic absorbing means.

29. A device as claimed in any of Claims 22 to 28 characterised in that the therapeutic agent is an anti-clotting agent.

30. A device as claimed in any of Claims 22 to 29 characterised in that the therapeutic agent is an anti-coagulating agent.

31. A device as claimed in any of Claims 22 or 30 characterised in that the therapeutic agent is suitable for dissolving blood clots.

32. A device as claimed in any of Claims 22 to 31 characterised in that the therapeutic agent is a preventative drug for preventing inflammation of tissue in contact therewith.

33. A device as claimed in any of Claims 22 to 32 characterised in that the therapeutic agent is an antibiotic.

34. A device as claimed in any of Claims 22 to 33 characterised in that the therapeutic agent is an antiviral agent.

35. A device as claimed in any of Claims 22 to 34 characterised in that the therapeutic agent is an agent for use in gene therapy.

36. A device as claimed in any preceding claim characterised in that a sealing means is provided on the device for sealing a puncture in a wall of the heart defining a part of the cavity punctured during placement of the device in the cavity.

37. A device as claimed in any preceding claim characterised in that a locating means extends from the device for projecting into a wall of the heart defining a part of the cavity for securely locating the device in the cavity.

38. A device as claimed in Claim 37 characterised in that the locating means is adapted for projecting through an opening in the heart wall, and a securing means is provided co-operating with the locating means for securely locating the device in the cavity.

39. A device as claimed in Claim 38 characterised in that the securing means co-operates with the locating means and the device for clamping the device to the heart wall.

40. A device as claimed in Claim 38 or 39 characterised in that the securing means is provided by the sealing means.

41. A device as claimed in any of Claims 38 to 40 characterised in that the securing means acts to seal the opening through which the locating means extends.

42. A device as claimed in Claim 40 or 41 characterised in that the sealing means is provided for sealing an opening in the heart wall which is formed for providing access to the cavity for placing the device therein.

43. A device as claimed in any preceding claim characterised in that the device is for correcting mitral valve regurgitation resulting from inversion of leaflets of the mitral valve, and the abutment means is for locating in the left atrium of the heart for abutting the valve leaflets when the mitral valve is in the closed state.

44. A device as claimed in Claim 43 characterised in that a closure means is provided on the device for closing off the left arterial appendage of the left atrium.

45. A device as claimed in Claim 44 characterised in that the closure means is located on the retaining means.

46. A device as claimed in Claim 44 or 45 characterised in that the closure means is a patch type closure means.

47. A device as claimed in any of Claims 43 to 46 characterised in that the closure means comprises a sleeve extending around the device.

48. A device as claimed in Claim 47 characterised in that the sleeve extends around the retaining means.

49. A device as claimed in any of Claims 43 to 48 characterised in that the closure means is of fabric material.

50. A device as claimed in any of Claims 43 to 49 characterised in that the closure means is of a polymer material.

51. A device for correcting mitral valve regurgitation in the heart of a subject resulting from inversion of the leaflets of the mitral valve, characterised in that the device comprises an abutment means for locating in the left atrium of the heart for abutting the valve leaflets when the mitral valve is in a closed state, and a retaining means co-operable with the heart and the abutment means for retaining the abutment means in abutting engagement with the valve leaflets when the mitral valve is in the closed state for preventing inversion of the valve leaflets.

52. A device as claimed in any preceding claim for use in the correction of a leaflet valve in the heart of a subject for preventing backflow through the valve when the valve is in the closed state.

53. A device as claimed in any preceding claim for use in the correction of the mitral valve in the heart of a subject for preventing mitral valve regurgitation.

54. A device for use in the correction of a leaflet valve in the heart of a subject for preventing backflow through the valve in the closed state, characterised in that the device comprises an abutment means for locating in a cavity of the heart into which at least one of the leaflets of the valve inverts for abutting the valve leaflets when the valve is in the closed state, and a retaining means co-operating with the heart and the abutment means for retaining the abutment means in abutting engagement with the valve leaflets when the valve is in the closed state for preventing inversion of the leaflets.

55. A device for use in the correction of the mitral valve in the heart of a subject for preventing mitral valve regurgitation, characterised in that the device comprises an abutment means for locating in the left atrium of the heart for abutting the valve leaflets when the mitral valve is in a closed state, and a retaining means co-operable with the heart and the abutment means for retaining the abutment means in abutting engagement with the valve leaflets when the mitral valve is in the closed state for preventing inversion of the valve leaflets.

56. Use of the device as claimed in any preceding claim for correcting inversion of the leaflets of a leaflet valve in the heart of a subject.

57. Use of the device as claimed in any preceding claim for correcting for mitral valve regurgitation in the heart of a subject.

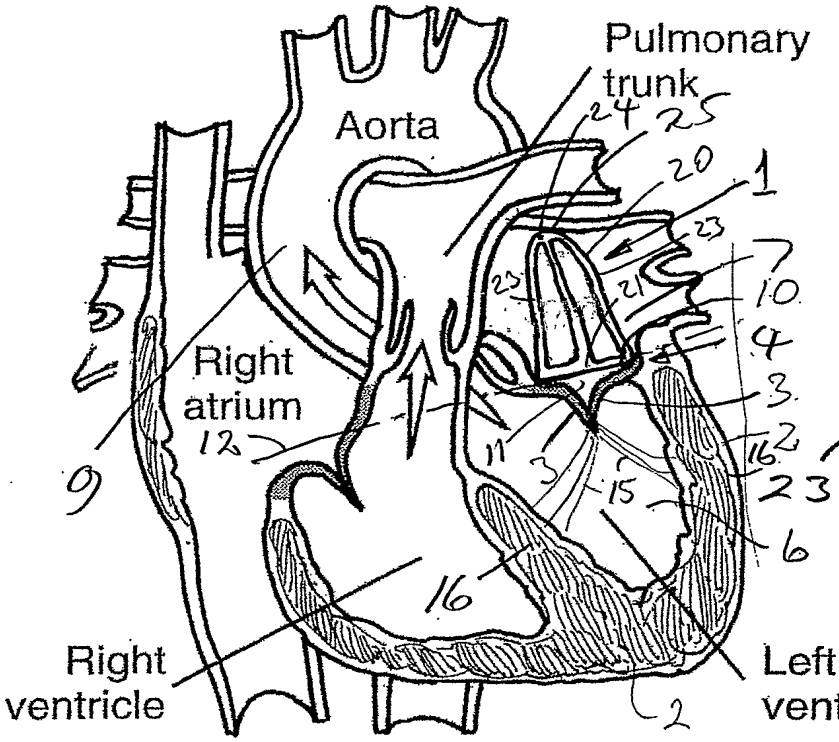

FIG 5

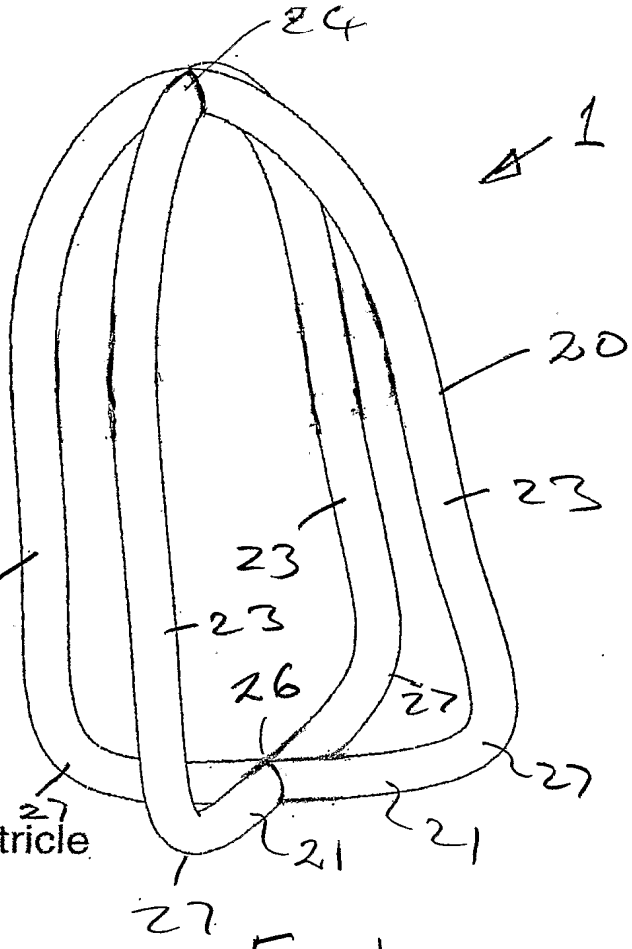

FIG 1

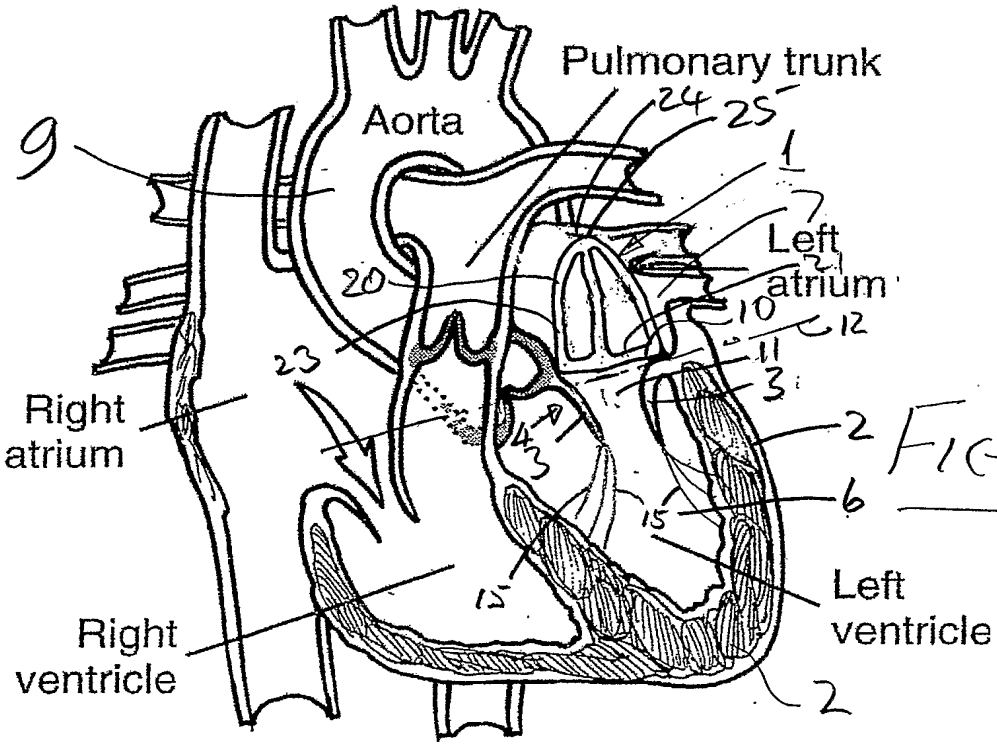

FIG 4

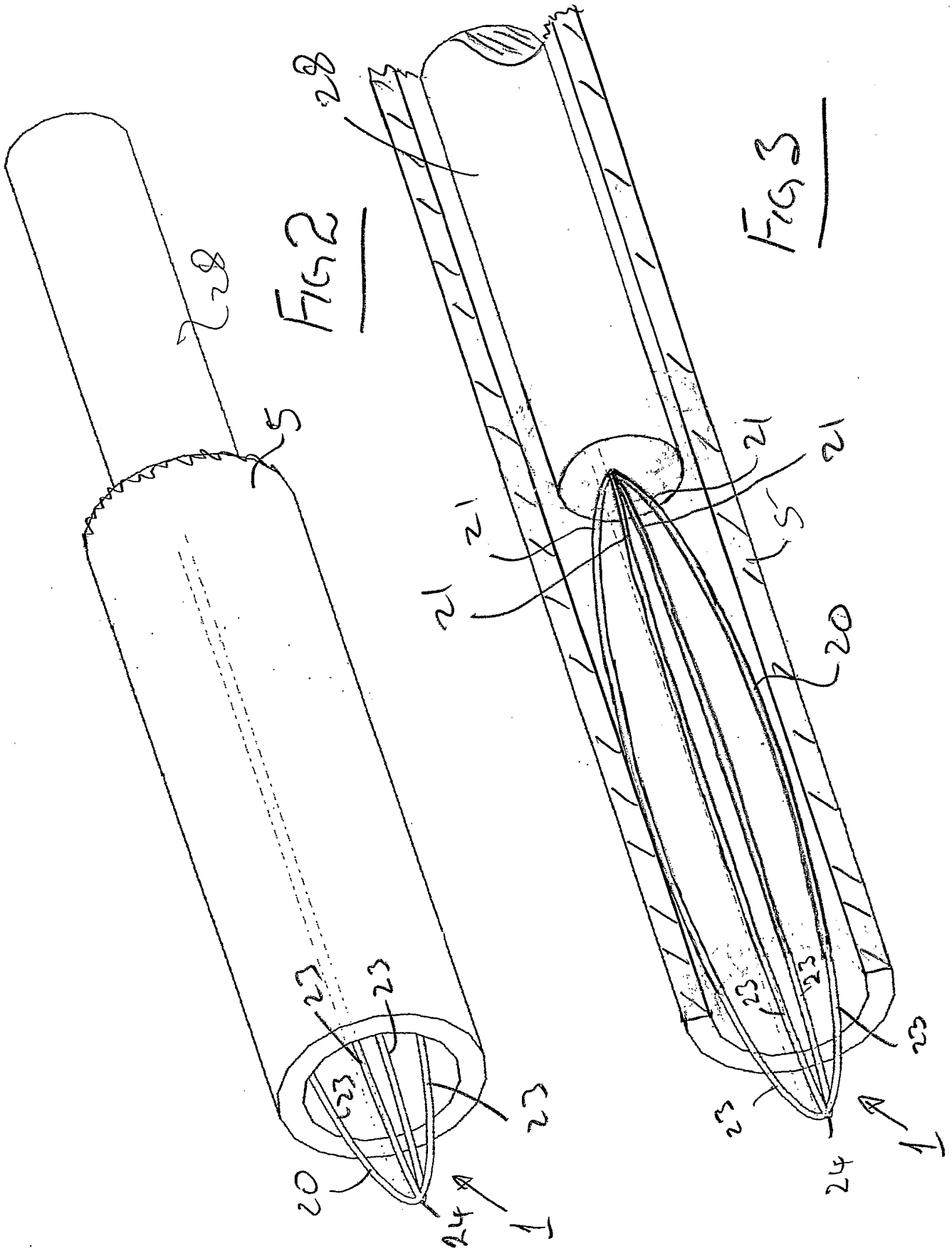
28
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Fig 2
28
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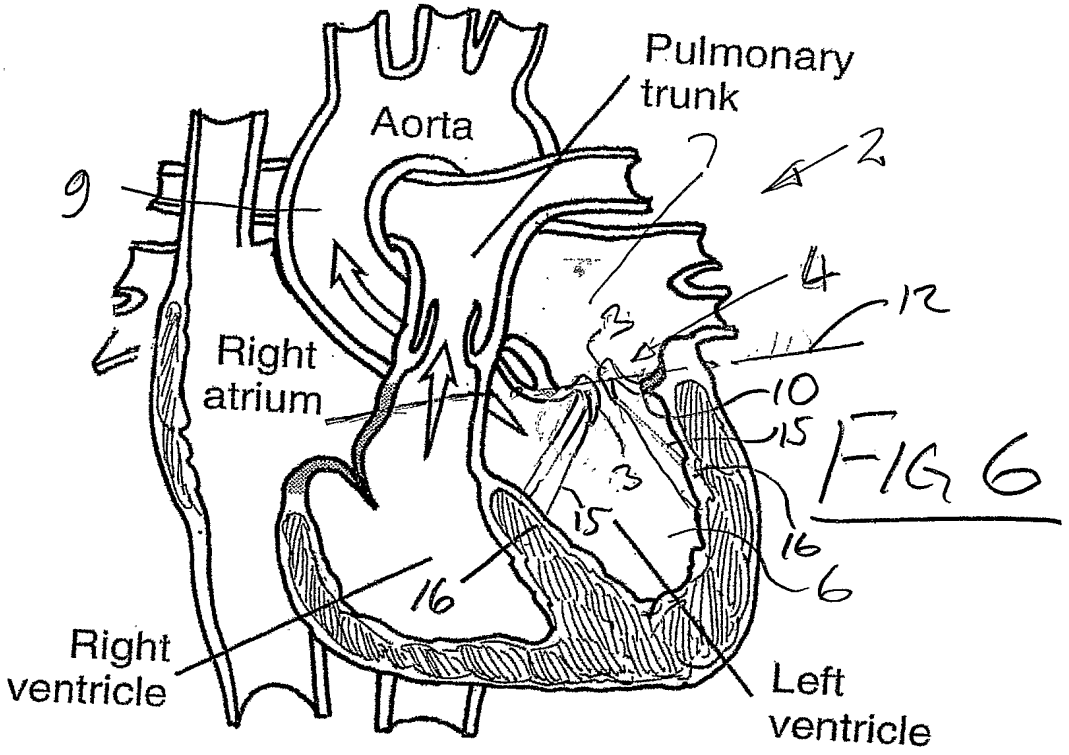
Fig 3


Pulmonary trunk
Aorta
9
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2
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3
Right atrium
10
15
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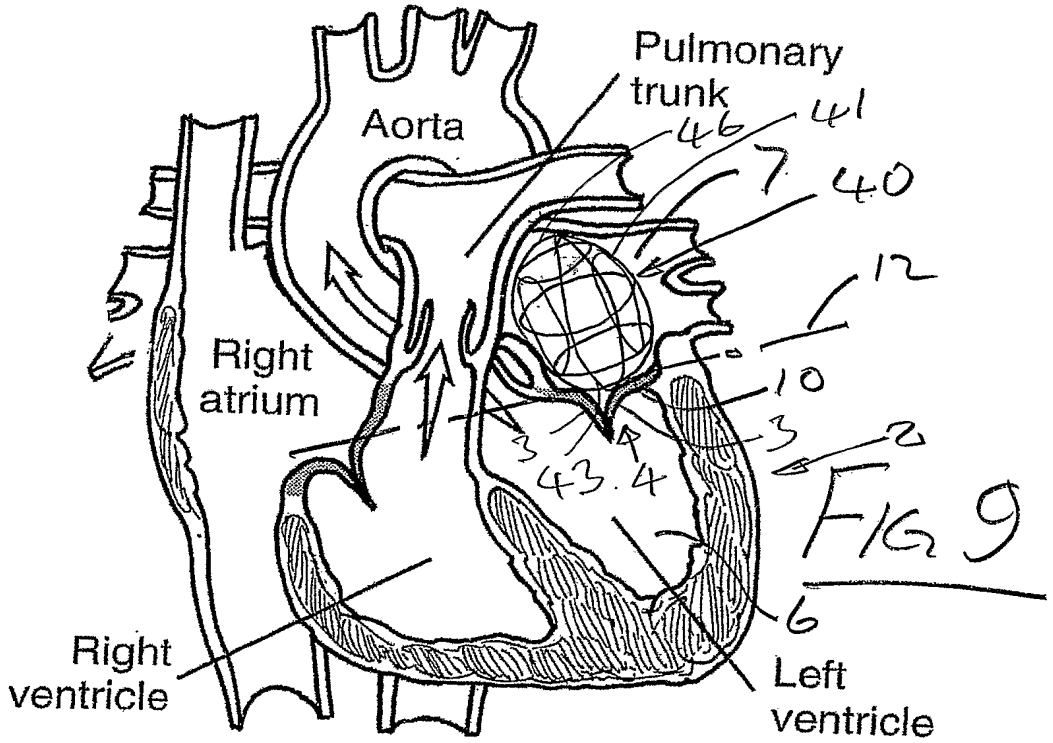
15
16
6
16
Right ventricle
Left ventricle

FIG 6


Pulmonary trunk
Aorta
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41
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40
12
Right atrium
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3
2
43
4
6
Right ventricle
Left ventricle

FIG 9

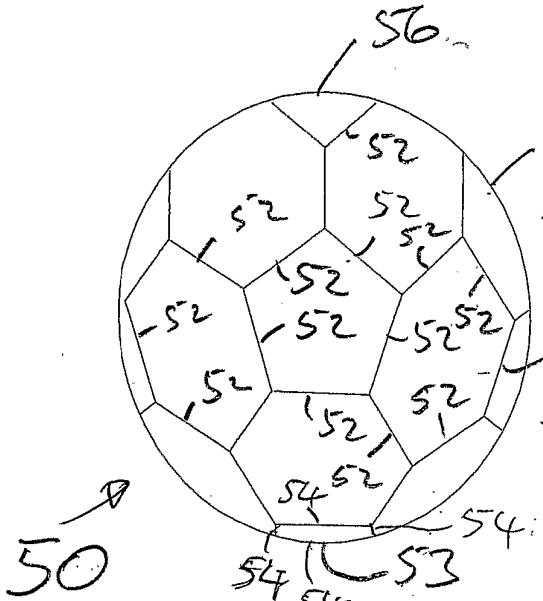

FIG 10

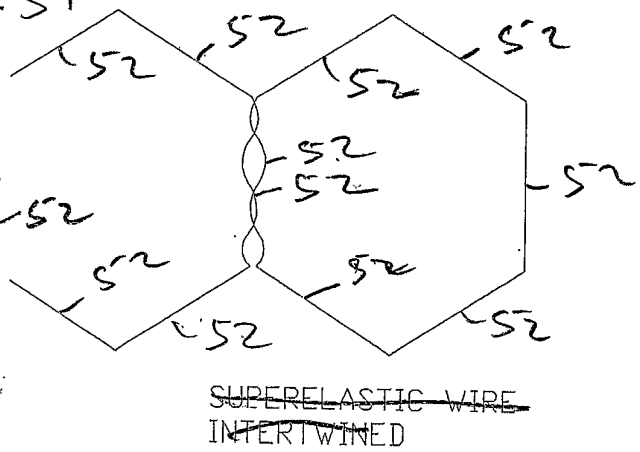

FIG 11

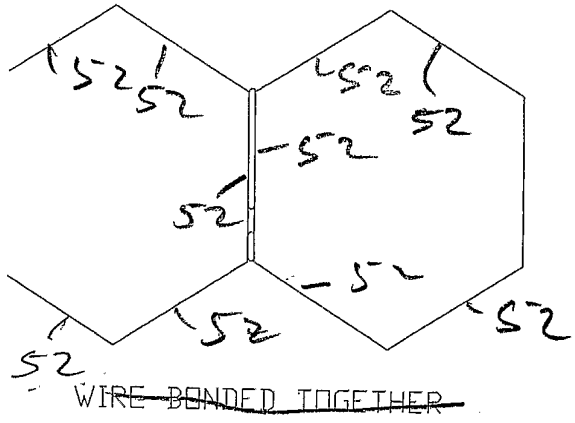

FIG 12

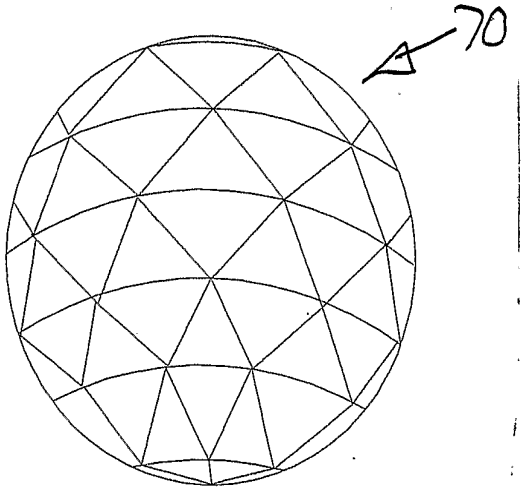

FIG 14

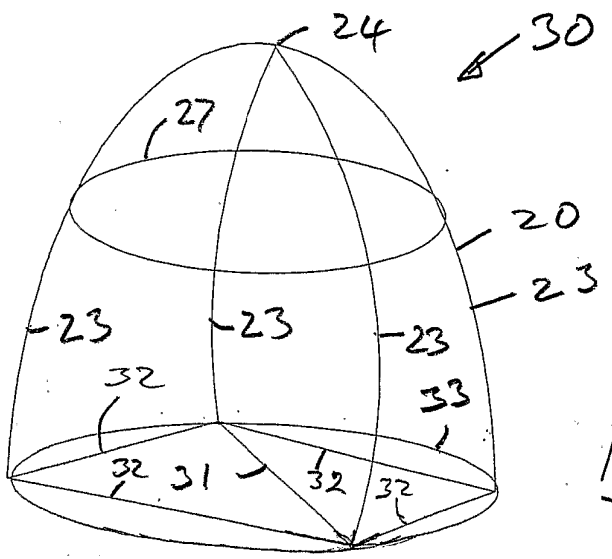

FIG 7

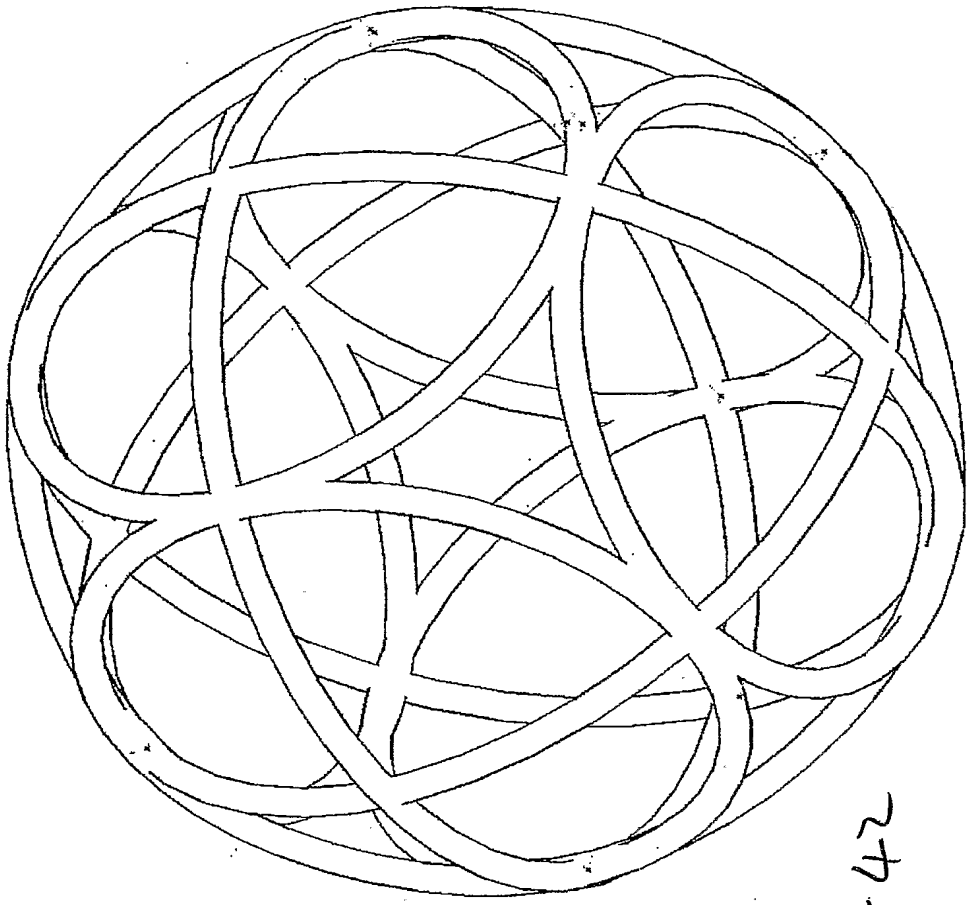

FIG 13

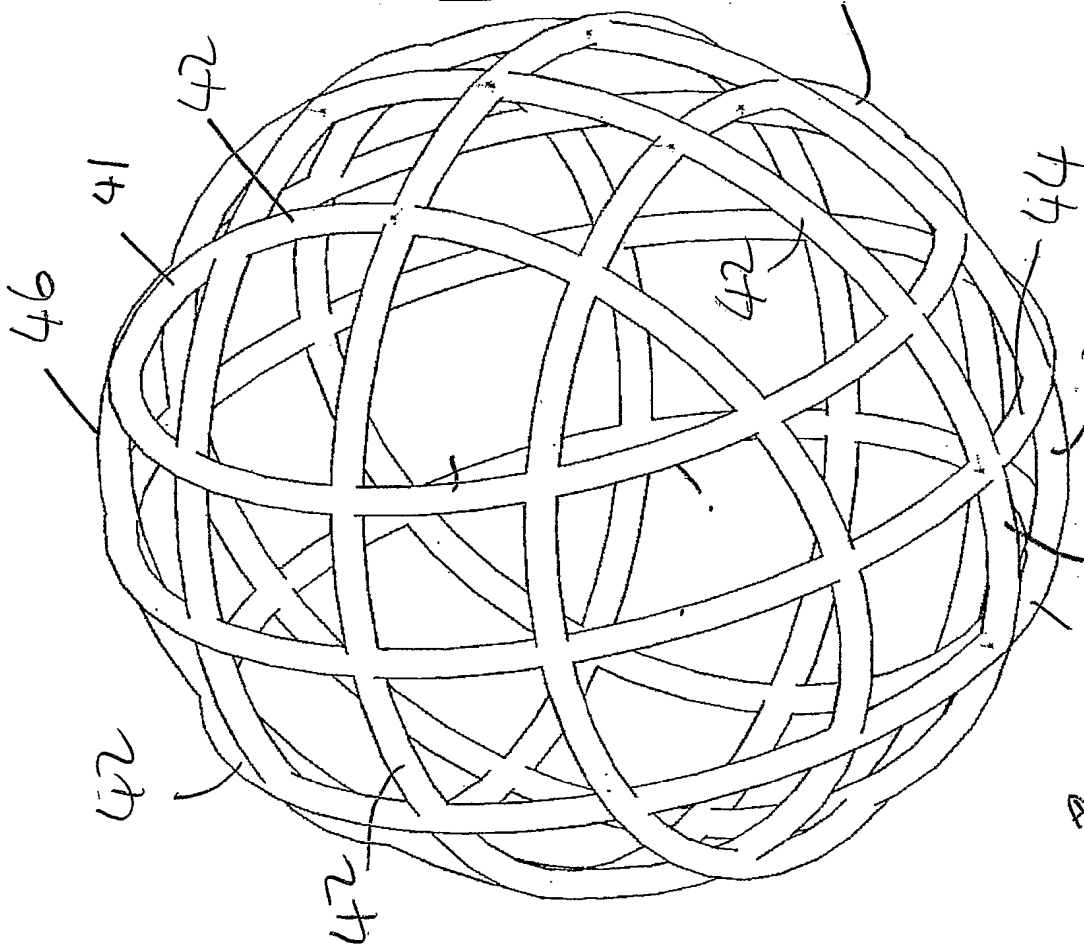

FIG 8

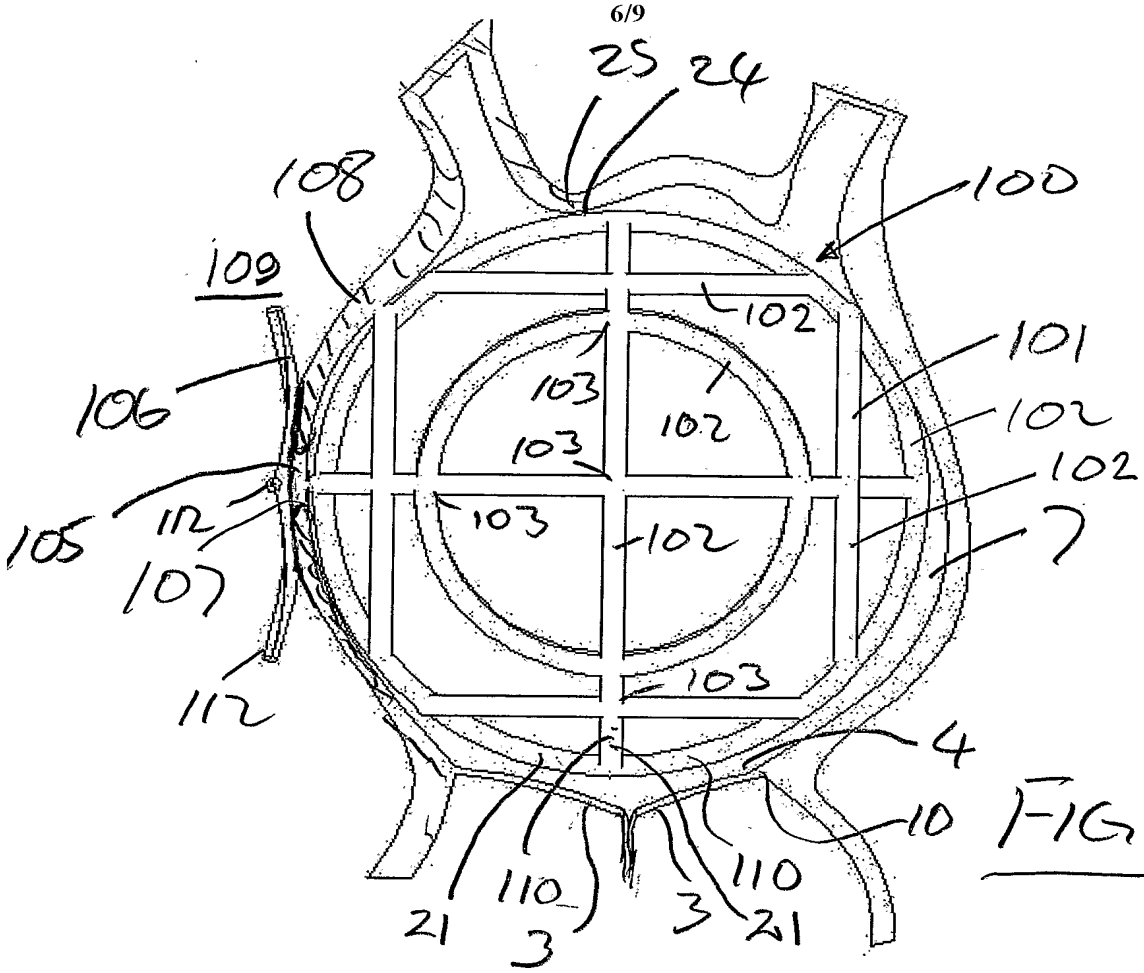
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FIG 20

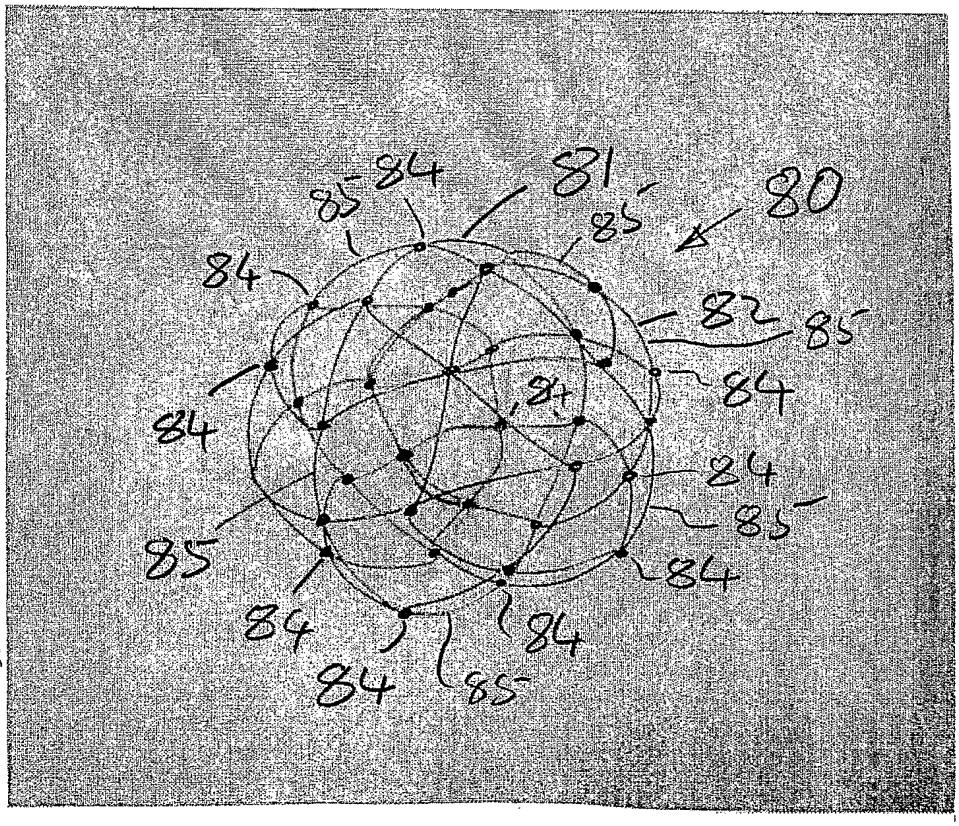
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FIG 15

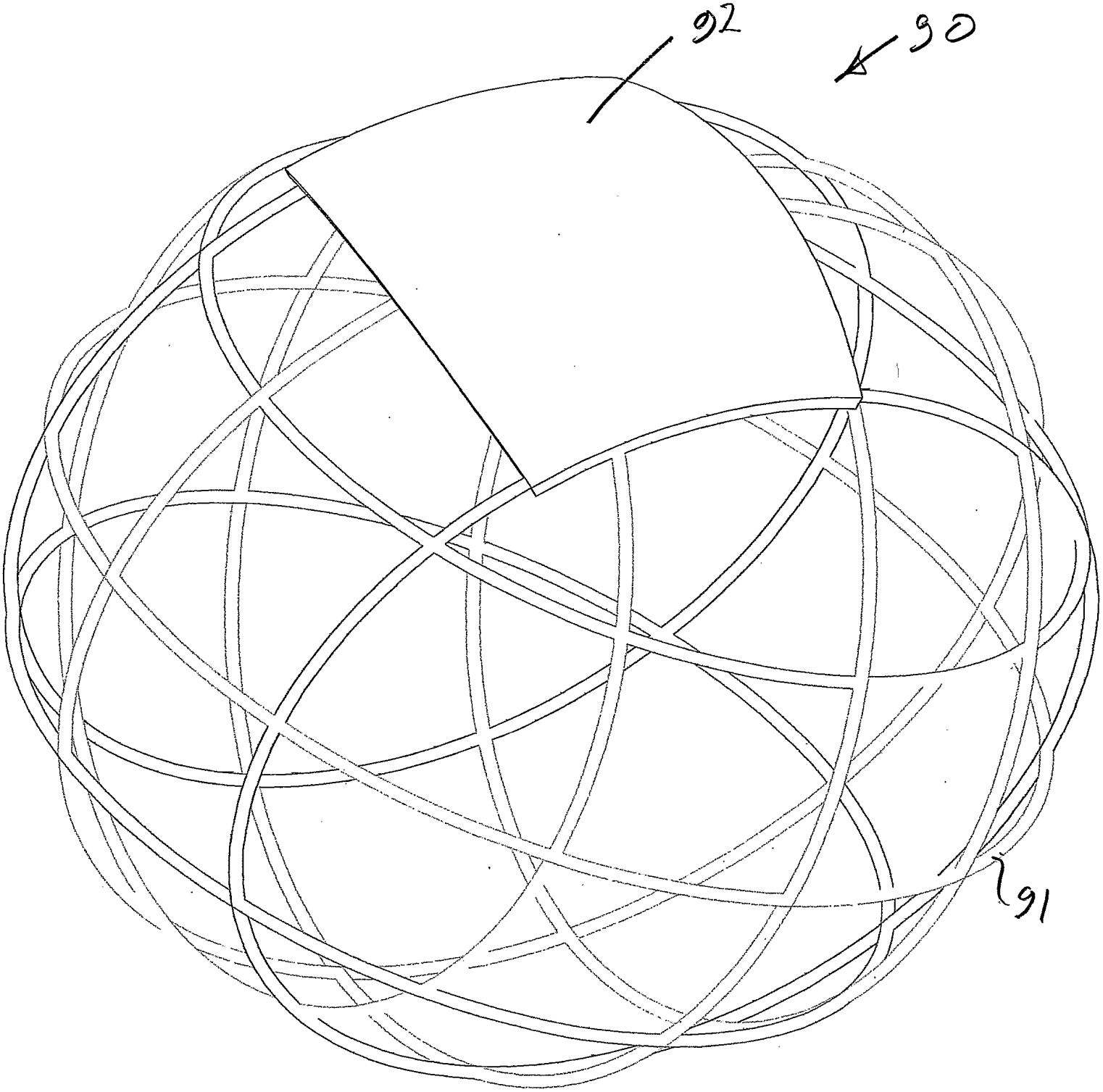
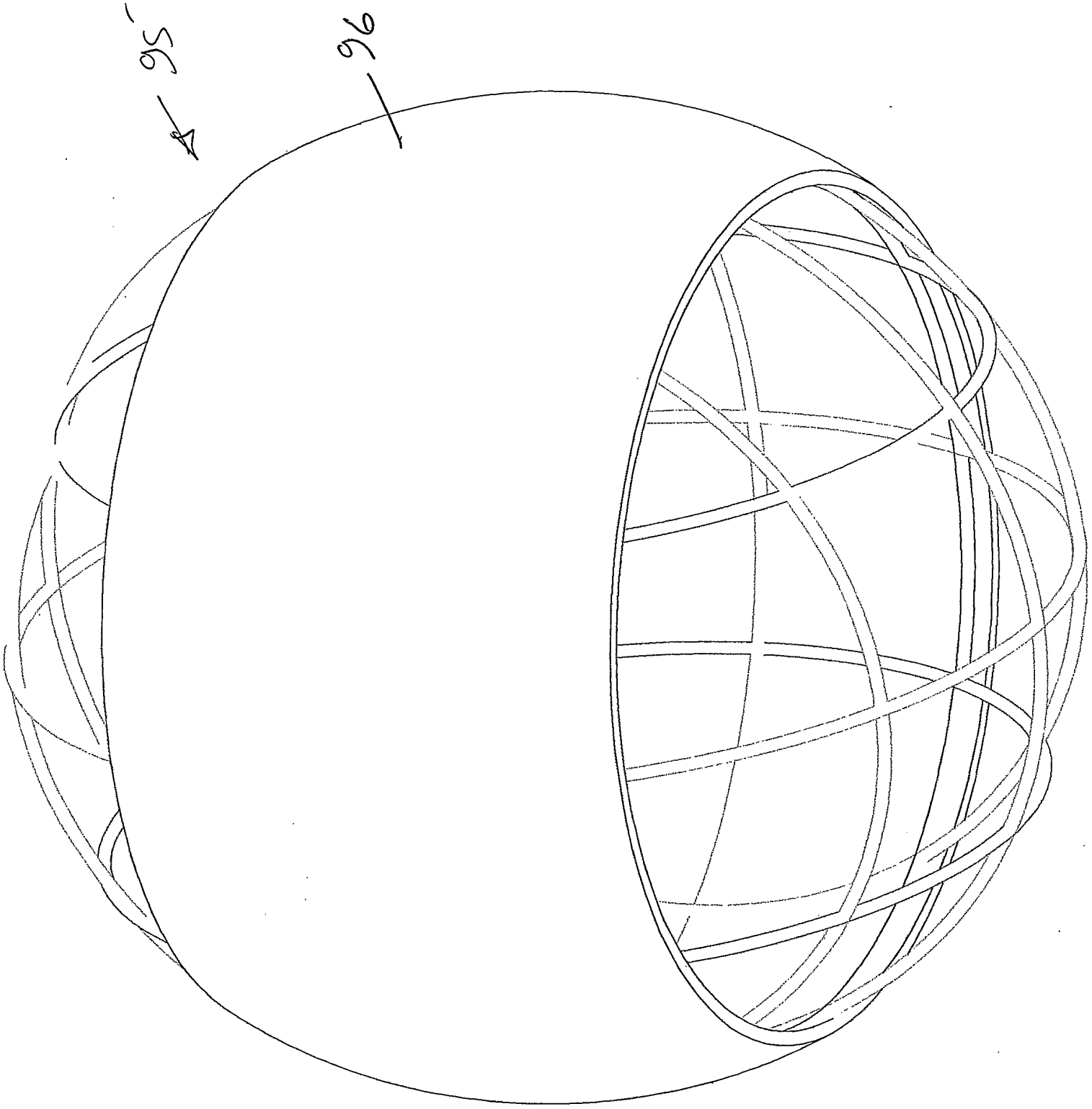


FIG 16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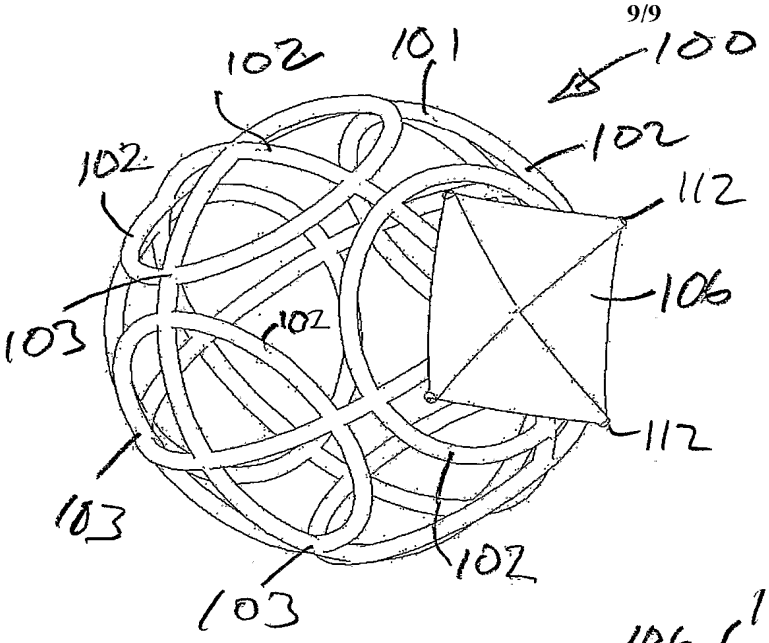

FIG 18

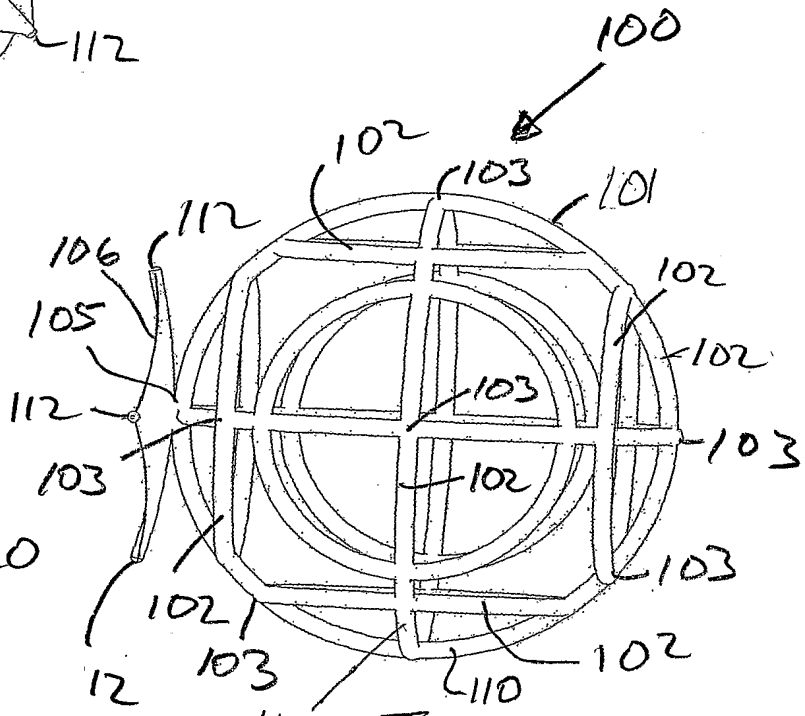

FIG 19

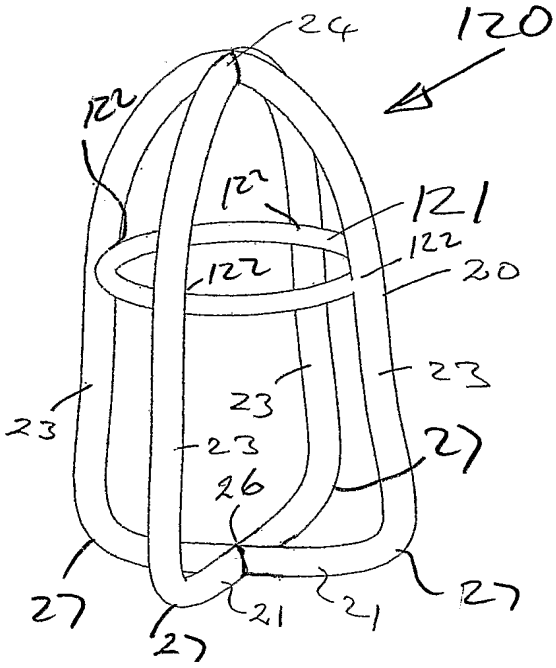

FIG 21

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IE2004/000097

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/028558 A (MACHOLD TIMOTHY R ; SOSS RICK A (US); CHANG ROBERT T (US); MACOVIAK JO) 10 April 2003 (2003-04-10) page 7, line 15 - page 11, line 17; figures 16-19,27-33	1-35, 37-39, 43,51-55
A	US 2003/083742 A1 (SPENCE PAUL A ET AL) 1 May 2003 (2003-05-01) the whole document	1,51,54, 55

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 October 2004	28/10/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Newman, B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IE2004/000097

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 56, 57
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IE2004/000097

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 03028558 A	10-04-2003	CA 2455444 A1	10-04-2003
		CA 2462254 A1	10-04-2003
		EP 1434621 A2	07-07-2004
		EP 1434542 A2	07-07-2004
		WO 03028802 A2	10-04-2003
		WO 03028558 A2	10-04-2003
		US 2004138745 A1	15-07-2004
US 2003083742 A1	01-05-2003	US 2004088047 A1	06-05-2004